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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,899	04/12/2001	Jean-Marc Balloul	032751-052	1686

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Norman H. Stepno
BURNS, DOANE, SWECKER & MATHIS, L.L.P.
P.O. Box 1404
Alexandria, VA 22313-1404

EXAMINER	
BOESEN, AGNIESZKA	
ART UNIT	PAPER NUMBER
1648	

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08/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/832,899	BALLOUL ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-7 and 11-27* is/are pending in the application.

4a) Of the above claim(s) *16,17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-7,18 and 24-27* is/are rejected.

7)☒ Claim(s) *3 and 11-15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed May 30, 2007 in response to the Office Action of March 2, 2007 is acknowledged and has been entered. Claims 2 and 10 have been canceled. New claim 27 has been added. Claims 1, 3, 5-7, 11-15, 18, and 24-26 have been amended. In view of the amendment to claim 1, reciting a specific embodiment such as the antibody fragment, claim 7 drawn to a specific antibody fragment is presently rejoined. Claims 1, 3, 5, 6, 7, 11-15, 18, and 24-27 are under examination in the present Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-3, 5, 6, 10-15, 18, 24, 25 and new claim 26 under 35 U.S.C. 112, first paragraph, as failing to comply with enablement requirement **is withdrawn** in view of Applicants arguments and amendments to the claims.

Rejection of claims 1-3, 5, 6, 10-15, 18, 24, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of Applicants arguments and amendments to the claims.

Claim Rejections - 35 USC § 102

Rejection of claims 1-3, 5, 6, 10, 11 18, 24, 25 and 26 under 35 U.S.C. 102(b) as being anticipated by Balloul et al (Cellular and Molecular Biology, 1994, Vol. 40, p.49-59) as evidenced by Vazquez et al. (Journal of Virology, 1998, Vol. 72, p. 10126-10137) **is withdrawn** in view of Applicants arguments and amendments to the claims.

New Rejections in view of Applicants' amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 18, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galmiche et al. (Journal of General Virology, 1997, Vol. 78, p. 3019-3027, in IDS of 10/7/2003) in view of Chung et al. (Journal of Virology, 1998, Vol. 72, p. 1577-1585).

Claims are drawn to a IMV poxviral particle having targeted infection specificity towards tumor specific antigen, wherein the poxviral particle infects target cells by binding of at least one ligand moiety to an anti-ligand molecule localized at the surface of the target cell. The ligand moiety is an antibody fragment, which is fused to the N-terminus of the expression product of the vaccinia virus A27L gene. The claims are drawn to IMV vaccinia virus particle wherein at least a portion of the expression product of the vccinia virus A27L gene is removed and replaced with the ligand moiety.

Galmiche et al. teach IMV poxviral particle having targeted infection specificity towards tumor specific antigen ErbB2 (see the entire document, particularly the Methods on page 3020, right column, and Figure 1). Galmiche et al. teach IMV poxviral particle wherein the ligand moiety comprises an antibody fragment, which is a single chain antibody scFv from FRP5 antibody specific for ErbB2 (see page 3019). Galmiche et al. teach the antibody fragment fused with the extraviral portion of hemagglutinin envelope protein. Galmiche et al. does not teach the

antibody fragment fused to the N-terminus of the expression product of the vaccinia virus A27L gene.

Chung et al. teach that IMV vaccinia virus A27L protein mediates virus attachment to heparan sulfate moieties on target cells and that A27L protein is required for cell fusion. Chung et al. also teach that the deletion of N-terminal region of A27L protein eliminates fusion activity of vaccinia virus particles with target cells (see Discussion on page 1584).

Thus based on the teaching of Chung et al., it would have been obvious to fuse ligand moiety such as an antibody or any other ligand having binding specificity to tumor associated antigens with the N-terminus of the expression product of the vaccinia virus A27L gene, for the purpose of making an IMV vaccinia particle having targeted infection specificity.

The person of ordinary skill in the art would have been motivated to provide Galmiches' IMV vaccinia virus particle having infection specificity towards tumor specific antigen comprising a ligand moiety fused to Chung's N-terminal region of A27L protein, because Chung et al., teach that the N-terminal region of A27L is required for virus fusion with target cells, and because the skilled artisan would not desire infecting normal cells. It is understood that the target cells of the present invention are tumor cells expressing tumor associated antigen and therefore normal cells should not be infected with the IMV vaccinia virus particle of the present invention. Thus in order to ensure that the IMV vaccinia virus particle infects only tumor cells and not normal cells, the skilled artisan would have been motivated to fuse ligand moiety with the external part of the A27L gene that is the N-terminus of A27L which function is to facilitate the infection of normal cells, and that way confer the specificity to the IMV vaccinia virus particle. In another words, if the IMV vaccinia virus particle comprised only the A27L localized at the

surface of the viral particle this viral particle would infect all cells expressing heparan sulfate receptor including normal cells and thus would not have infection specificity. It would have been obvious to provide a composition comprising IMV vaccinia virus particle and a pharmaceutically acceptable carrier because compositions formulated for in vivo administration typically comprise a pharmaceutical carrier.

With regard to claims requiring that at least a portion of the expression product of the vccinia virus A27L gene is removed and replaced with the ligand moiety, the skilled artisan would have been motivated to remove a portion of the A27L gene in order to facilitate the fusion of A27L with the ligand moiety, and in order to ensure that the A27L is no loner functional and does not mediate infection of IMV vaccinia virus particle with normal cells.

One would have had a reasonable expectation of success to provide the IMV vaccinia virus particle of the present invention because the recombinant technology used to make recombinant viruses has been well established in the art.

Therefore the present invention would have been obvious to the ordinary artisan at the time when the invention was made.

Claims 6, 7, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galmiche et al. (Journal of General Virology, 1997, Vol. 78, p. 3019-3027, in IDS of 10/7/2003) in view of Chung et al. (Journal of Virology, 1998, Vol. 72, p. 1577-1585) as applied to claim 1 and further in view of Schumacher et al. (The Journal of Histochemistry and Cytochemistry, 1998,Vol. 46, p. 127-134).

Galmiche and Chung teach IMV vaccinia virus particle having infection specificity towards tumor specific antigen comprising a ligand moiety fused to N-terminal region of A27L protein. Galmiche and Chung do not teach SM3 antibody fragment that recognized MUC-1 antigen. Schumacher teaches SM3 antibody specifically recognizing MUC-1 antigen.

It would have been obvious to use Schumancher's antibody SM3 specific for MUC-1 in the IMV vaccinia virus particle described by the combination of Galmiche and Chung. One would have been motivated to substitute Galmiche's FRP5 antibody specific for ErbB2 in the IMV vaccinia virus particle with Schumancher's antibody SM3 specific for MUC-1, or with any other antibody with specificity to the tumor antigen, because tumor antigens and the antibodies that bind the tumor antigens are known in the art. The inventive concept is the construct: an IMV particle with a targeting moiety fused to the A27L expression product; the inventive concept is not necessarily the ligand moiety itself.

One would have a reasonable expectation of success to provide the construct of the present invention because IMV vaccinia virus particles with binding specificity conferred by antibody fragment recognizing tumor antigens have been made in the art at the time the present invention was made as evidenced by Galmiche.

Therefore the present invention would have been obvious to one of ordinary skill in the art at the time when the invention was made.

Claim Objection

Claims 3, and 11-15 are objected to because the claims depend on rejected claims.

Conclusion

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Thus, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday – Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.

/Stacy B. Chen/ 8-17-2007
Primary Examiner, TC1600